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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/881,572	06/14/2001	Monica Judith Roth	601-1-095N	5861

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EXAMINER

WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 01/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/881,572

Applicant(s)

ROTH ET AL.

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 07 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 1-14, 17, 20-25 and 27-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-19 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7. 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group V claims 15-19 and 26 and the species, retroviruses in Paper No. 9 are acknowledged. The traversal is on the ground(s) that even with patentably distinct inventions, restriction is not required unless one of the following reasons appear: separate classification, separate status in the art or different field of search. Applicants further argue that the search and examination of the entire application can be made without serious burden to the examiner. This is not found persuasive because as applicants stated above, the restriction is proper if a different field of search exists. The searches for the different groups extend to literature searches, which are not coextensive with the Patent searches (U.S. and foreign). Also, the groups have acquired a different status in the art because of their recognized divergent subject matter. Due to the different limitations encompassed by each groups, examination of each groups will impose undue burden to the examiner. A prior art reference anticipating one group would not render obvious the other groups that contains different limitations and/or subject matter.

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The requirement is still deemed proper and is therefore made FINAL.

Claims 1-14, 17(non-elected species), 20-25 and 27-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

Claims 15-19 and 26 are under examination.

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors (grammatical, typographical and idiomatic). Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-19 and 26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described

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in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification fails to provide an adequate written description of the different population of host cells that can be infected by a multitude of different virus. The specification does not describe the kind or type of viruses contained in a random library with differing amino acids in the envelope protein. There is no description as to how a random library for each virus is created such that each or all kinds of viruses are represented in the library. Neither does it describe the kind of host range a particular virus infects nor how one isolates or identifies each particular virus that infects a particular host in a population of infected cell. A virus attaches itself to any host cell that it comes in contact with. There is no distinguishing characteristic of the different random display viruses or the host cells that enables isolation of one infected host cell from the other. Nor is there a general method steps that can isolate one virus or infected cell from the other viruses. The Example provided in the specification recites for a specific virus, Felv A. Even with this specific virus, applicants stipulate selection of Felv because the Felv-A Env

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receptor binding domain is a much simpler structure, its receptor determining region has been well characterized and shown to consist of a short stretch of amino acids. It is apparent that this is not so for all retroviruses family, let alone, for any or all type or kind of viruses. Battini(PNAS) discloses at page 1385, col. 1 that "although present in many copies in mouse genome, ..murine leukemia viruses cannot infect cells from laboratory mice because of the lack of a functional cell surface receptor required for virus entry."

In any library system encoded by oligonucleotide synthesis one cannot have complete control over the codons that will eventually be incorporated into the peptide structure. This is especially true in the case of codons encoding stop signals (TAA, TAG, TAG). In the synthesis with NNNN as the random region, there is a chance that the codon will be a stop codon. In a peptide of 10 residues there is an unacceptable high likelihood of the peptides will prematurely terminate.

Accordingly, the specification fails to provide an adequate written description for the claimed invention covering numerous generic variables.

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-19 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the steps between administration and isolation. Claim 15 is unclear as to the method of administering a random peptide library i.e., how administration is done to a host cell. It is not clear as to the steps as to how a particular virus (retrovirus) in an infected host cell is isolated from one another. There is no correspondence between the preamble "transfer of nucleic acid to a host cell" and the body of the claim that "infects a host cell". If this is the same, then the use of different language provides for confusion.

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B. In claim 16, the recitation of "a method of claim 15 wherein each member of the plurality codes, on the same nucleic acid molecule....." is vague and broaden the base claim 15. Claim 15 does not recite that the plurality of amino acid codes or recites a nucleic acid molecule or a coding for both an exterior protein and a cell selection marker. Reciting "A method" in claim 16 is indefinite since the method is already recited in claim 15. It is suggested that "A" be changed to -The--.

C. Claim 26 is confusing as to how a retrovirus is created. Claim 15 does not recite for creation of a retrovirus. Also, this claim depends on the non-elected claim 20 (and elected claim 15). It is suggested that applicants delete claim 20.

D. Claim 19, "the size" lacks antecedent basis of support from the base claim. Furthermore, it is not clear as to which size of the plurality is being referred to.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15-18 and 26 are rejected under 35 USC 102(e) anticipated by Nolan (6,455,247).

Nolan discloses at col. 2, lines 21-51 a method of introducing a molecular library of retroviruses comprising different randomized nucleic acids into a plurality of cells. Each of the nucleic acids comprises a different, generally

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randomized, nucleotide sequence. The plurality of cells is then screened, for a cell exhibiting an altered phenotype (i.e., isolating the virus that infects cell, as claimed). See also, col.16, line 21 up to col. 21, line 38. The Examples, col. 35, line 10 up to col.47. Accordingly, Nolan discloses a specific method step using specific random library of retroviruses that anticipates the broad claimed method steps.

Claims 17 and 19 are disclosed by Nolan at col. 20, line 66 up col. 21, line 12.

Claim 16 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Russell et al (U.S. 5,723,287) or Buchholz (Nature Biotechnology).

Russell discloses at page 12, second complete paragraph, a retrovirus created by the method of generating a diverse library of recombinant retroviruses and transfection of retroviral plasmids into retroviral packaging cells. The library size of 10 retroviral genetic display packages is used. A methods of selection (based on the presence of the viral nucleic acid in the infected target cell) to isolate nucleic acid sequences encoding polypeptides which, when displayed on the surface of a recombinant virus, can increase the efficiency with which the

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virus delivers its encapsidated nucleic acid to the interior of a eukaryotic target cell.

Buchholz et al discloses at page 952, Figure 1 retroviruses obtained by a method of transfecting with plasmids encoding a library of retroviruses, moMLV particles a mammalian cells, HT1080Rec-1 cells. Buchholz further discloses the method of isolating the virus, which was concentrated from the cell supernatant by ultracentrifugation. See the detailed description at page 954, Experimental protocol. Buchholz or Russell discloses substantially identical retroviruses, as claimed. Where the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See *In re Ludtke*, supra. Whether the rejection is based on "inherency" under 35 USC 102, on "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same as is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. See *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972); *In re Best* 195 USPQ 430 (CCPA 1977).

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Claim Rejections - 35 USC § 103

Claims 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buchholz et al or Russell in view of Larocca (6,451,527).

Each of Russell and Buchholz is described above. Russell or Buchholz fails to disclose a method with a random display library of viruses. Larocca discloses at col. 6, lines 14-60 and col. 4, line 55, a random or selection mutations of libraries for improved gene delivery. It would have been obvious to one having ordinary skill in the art to use a random display library in the method of Buchholz or Russell as taught by Larocca. Larocca discloses that the use of random or selective mutations library provides for improved gene delivery. One having ordinary skill in the art would have been motivated to use a random display library since a random display library provides diverse populations of randomized expression products that effect sufficient range of cellular responses to provide one or more cells exhibiting a desired response.

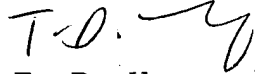
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
January 27, 2003